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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,776	03/11/2000	Pamela L. Zeitlin	49632	5882

7590

06/18/2002

Dike Bronstein Roberts & Cushman LLP  
130 Water Street  
Boston, MA 02109

EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/523,776

Applicant(s)

ZEITLIN ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period of Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 August 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 13, 14, 17-21 and 35-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16, 22-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.                      6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Claims 13, 14, 17-21, 35-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, ~~Claims 13, 14, 17-20, 35-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention~~ there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8 submitted August 30, 2001.
2. Applicant's election with traverse of invention group I, claims 15, 16 and 24 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that all the invention is in the same class and subclass and the search of all the claims would not be an undue burden. This is not found persuasive because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or III, restriction for examination purposes as indicated is proper.
3. The claims have been examined insofar as their read on elected invention and species. Note the elected invention is a method for treating cystic fibrosis disease.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Objections*

Claims 29 are objected to because there are two claim 29s. Applicant is suggested to cancel one of the claims and add the canceled claim as new claim with proper numbering.

### *Claim Rejections 35 U.S.C 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12, 23, 25-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases such as, does not reasonably provide enablement for treating cystic fibrosis, alpha 1 anti-trypsin disease, Alzheimer's disease, Marfan, or Tay-sachs disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Claims are directed to a method for treating a disease modulated by protein expression. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claim recites treating a disease modulated by protein expression. Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue

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experimentation. In the instant case, only a limited number of diseases associated to particular protein expression is set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define how the claimed method would also be effective for other diseases which may be associated with the particular protein expression herein, and/or diseases associated with other protein expression. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all diseases modulated by protein expression, necessitating an exhaustive search for the diseases suitable to practice the claimed invention, absent undue experimentation. Further, in view of the complexity and unpredictability of protein expression, skilled artisan would have not expected that a compound modulating one protein expression would similarly modulating all protein expressions which may associated with any disease.

#### Claim

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 23, 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is a self-dependent claim. The claim is indefinite as to which claim it depends from.

Claims 30-31 are dependent claims of claim 29. Since there are 2 claim 29, it is unclear which claim they actually depend from.

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8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-12, 14-15 and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron (US Patent 4,764,521) in view of Rubenstein et al (IDS, CJ) and Welch et al. (U.S. Patent 5,981,592).

10. Herron teaches generally that substituted aryl carboxylic acids, including substituted 4-phenyl-3-butenic acid are known to be useful for treating respiratory disease such as cystic fibrosis. See, the abstract, columns 1-4, column 12, lines 5, column 17, lines 50-52.

11. Herron does not teach expressly the employment of unsubstituted aryl carboxylic acid, e.g., 4-phenyl-trans-3-butenic acid for treatment of cystic fibrosis.

12. However, Rubenstein et al. teaches unsubstituted aryl carboxylic acid, 4-phenylbutyric acid is also known to be useful for treatment of cystic fibrosis. See, particularly, the abstract. Welch et al. further teaches that a variety of aryl carboxylic acids are known to be useful for treatment of cystic fibrosis. See, the abstract, columns 6-7.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ 4-phenyl-trans-3-butenic acid for treating cystic fibrosis.

A person of ordinary skill in the art would have been motivated to employ 4-phenyl-trans-3-butenic acid for treating cystic fibrosis because aryl carboxylic acids, with substituent or without substituent on the aryl ring, and wherein the carboxyl group attached to the aryl group

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through either alkyl or alkenyl, are generally known to be useful for treating cystic fibrosis. The instant compound differing from the prior art compound only in the substituent on the aryl ring, or the double bond at the linker between the aryl and carboxylic group, would have been reasonably expected to be similarly useful for treating cystic fibrosis, absent evidence to the contrary. Regarding claim 22-23, note selecting and/or optimizing a administering method of a pharmaceutical agent is considered within the skill of artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

June 11, 2002